PERFORMANCE WORK STATEMENT
TITLE: "External Peer Review and Technical Support of Pesticide Regulatory Activities"

BACKGROUND

The U.S. Environmental Protection Agency's (EPA) Office of Pollution Prevention and Toxic Substances (OPPTS), in conjunction with its program offices, seeks technical support in the areas of science policy, risk assessment, and guideline development in order to fulfill requirements of the *Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA-as amended 1996).*

A central feature of *FIFRA* is that all pesticides in the United States must be registered with and approved by the EPA, unless specifically exempted (FIFRA section 25), prior to the manufacture, sale and distribution to ensure that the pesticide poses no serious risks to human health or the environment when used according to its label. Within EPA's OPPTS, the Office of Pesticide Programs (OPP) is responsible for all registration activities for pesticides, including scientific review and risk-benefits determinations. Several registration and scientific divisions in OPP are involved in these registration activities, including the Biopesticides and Pollution Prevention Division (BPPB), the Registration Division (RD), Health Effects Division (HED), Environmental Fate and Effect Division (EFED), and the Biological and Economic Analysis Division (BEAD). OPP evaluates the submitted scientific data, and determines whether the data is adequate for making regulatory decisions.

In accordance with *FIFRA*, applicants wishing to register a pesticide product are required to submit to the EPA their proposed pesticide product's complete formula, physical and chemical characteristics, manufacturing process, quality control data, analytical methods, a proposed label, and laboratory data derived from the performance of studies necessary for the EPA to make a sound, scientific decision concerning the safety to human health and the environment of the claimed uses for the product. A detailed description of the tests and results of the studies must be included in the submission, and with rare exceptions, these studies must be performed in accordance with protocols published in the OPPTS Test Guidelines. In general, a separate registration is required for each formulation, with the exception of alternate formulations that are similar enough to the basic formulation so as not to change its safety, physical properties, or efficacy. Each claimed use of the pesticide must be also be supported by the submitted data. The data requirements include human and environmental health effects-related toxicology and exposure (including environmental fate), data demonstrating the benefits and economic advantages expected and product performance data from the use of the registered pesticide. Data requirements are established by regulation and can include additional studies when determined appropriate to allow the Agency to make a regulatory decision. Registrants include companies that manufacture, sell and/or distribute pesticide products, including state and federal agencies. Additional data may be obtained from other sources, such as peer-reviewed, published scientific or other open literature, incidence data, the states, Indian tribes, cities, municipalities and private citizens, and can be used by EPA to determine whether the proposed uses for a pesticide product may pose unreasonable adverse effects to human health and the environment.

OPP's review process includes hazard identification, exposure analysis, risk characterization, and risk assessment. Scientific staff prepare Data Evaluation Reports (DERs)

summarizing the results of the studies, and document their own interpretations and conclusions in internal memoranda and other risk assessment documents. These documents are subject to peer review, both internal and when novel or especially significant concerns or risks are identified, through the *FIFRA* Scientific Advisory Panel.

All risk and benefit assessments and peer reviews are performed to allow EPA to determine whether a pesticide and its proposed uses are eligible to be registered in accordance with the standards of *FIFRA.* If the use of a pesticide has the potential for residues to end up in food commodities and/or animal feed, EPA must also determine whether there are sufficient data to meet the standards of the *Federal Food, Drug and Cosmetic Act (FFDCA)* for the pesticide residues are considered to be food additives and regulated as such under that statute. OPP also evaluates requests to waive specific data requirements (based upon scientifically sound rationales), reviews the Confidential Statements of Formulations (CSFs), and proposed pesticide labels for new pesticides submitted for registration and amendments to existing registered products. Upon completion of all of its reviews, OPP will make a registration decision. Except under certain circumstances (as permitted under Section 3(c)(7) of *FIFRA*, if the database is found to be insufficient, additional data will be required of the registrant before a registration will be issued. When a new product is registered (or an existing product is amended), the registrant is presented with a notice of registration and a final label, stamped "Acceptable," in accordance with *FIFRA.* Each product is assigned a unique registration number, designated as "EPA Reg. No." on the product's label. Depending upon the confidentiality of the data, EPA will make this information available to interested parties through public dockets, publications in the *Federal Register*, the Freedom of Information Action (FOIA), and public databases, such as the *Integrated Risk Information System (IRIS).*

Prepared and maintained by the EPA, *IRIS* is an electronic database containing information on human health effects that may result from exposure to various chemicals in the environment. *IRIS* was initially developed for EPA staff in response to a growing demand for consistent information on chemical substances for use in risk assessments, decision-making and regulatory activities. The information in *IRIS* is intended for those without extensive training in toxicology, but with some knowledge of health sciences. The heart of the *IRIS* system is its collection of data files covering individual chemicals. These chemical files contain descriptive and quantitative information in the following categories: (1) Oral reference doses and inhalation reference concentrations (RfDs and RfCs, respectively) for chronic noncarcinogenic health effects, and (2) hazard identification, oral slope factors, and oral and inhalation unit risks for carcinogenic effects. The following hyperlink provides access to the *IRIS* database home page: http://www.epa.gov/iris/

The EPA is also required to conduct a re-evaluation of every pesticide active ingredient every 15 years. This process is known as Registration Review. It can include conducting new risk assessments; determining that additional data is needed to ensure that the pesticide products are up to the current scientific and legal standards required by *FIFRA* and *FFDCA*, reviewing new data submitted to support the active ingredient, updating existing registration documents such as Reregistration Eligibility Documents (REDs) or Biopesticide Registration Action Documents (BRADs), and reviewing labels to determine what impact a Registration Review decision makes to the currently approved label.

SCOPE OF WORK

The purpose of this contract is to support OPP and Agency position documents, reviews, and scientific technical assessments of potential hazards, exposures, and risks of pesticides and their components to human health and the environment. It may provide support when needed to the Offices of Water (OW) and/or Office Solid Waste (OSW) by the review of Criteria or Health Risk Assessment Documents.

In addition, the contractor shall create DERs including converting information such as the materials and methods of a study into a format specified by the Program Office(s) and including secondary and *Quality Assurance (QA)* contractor reviews, as specified. The contractor may be tasked to draft risk assessments, final rules for tolerances or tolerance exemptions, and regulatory documents such as BRADs.

DISCUSSION OF PERFORMANCE OBJECTIVES (TASKS):

Note: Individual task assignments will specify work for one or more of the following performance objectives (tasks), depending on data submissions from registrants, as well as any applicable scientific issue.

The requirements contained in this contract are considered to be performance-based, focusing on the Agency's desired results and outcomes. The contractor shall be responsible for determining the most effective means by which these requirements will be fulfilled. In order to fulfill the requirements, the contractor shall design innovative processes and systems that can deliver the required services in a manner that will best meet the Agency's performance objectives. This performance-based requirement represents a challenge to the contractor to develop and apply innovative and efficient approaches for achieving results and meeting or exceeding the performance objectives, measures, and standards described below. The Agency will monitor the contractor's performance in accordance with the Quality Assurance Surveillance Plan.

Under this performance work statement, the Government defines the desired outcome and the contractor proposes the most efficient methods to achieve acceptable results. Typical areas to be measured include cost control, timeliness and completeness of deliverables, problem resolution, business relations, quality of work performed, and whether or not the deliverable assists the Agency in meeting its objectives and goals as identified in the work assignment.

In cases where performance objectives and minimum Acceptable Quality Levels (AQLs) are not being met, the contractor will make every effort to immediately correct the problems to ensure customer satisfaction. If the problem is systemic, the contractor will submit a plan of corrective action to the WAM and COR.

TASK AREA (1): Review and Evaluation of Inert Pesticide Ingredients.

The contractor shall provide support for the review and evaluation of toxicology studies submitted to OPP on pesticide product inert ingredients in support of the establishment of tolerances or exemptions from the requirement of a tolerance for inert ingredients and the registration of pesticide products containing these inert

ingredients. The studies to be reviewed include studies in the areas of developmental and reproductive toxicity, subchronic toxicity, chronic toxicity, carcinogenicity, genotoxicity and neurotoxicity.

> **TASK AREA (1) Deliverable:** The contractor shall prepare written reports to include any other supporting documentation related to the evaluations conducted under this task area. *OPP* will supply the contractor with an estimated number of work hours for each type of guideline study. If the contractor finds that a review will take more hours than the estimated number of hours, they will notify OPP*'s* WAM and wait for approval before proceeding. If contractor reviews are found to be deficient by the Agency, the WAM will advise the contractor of the deficiencies and the contractor shall make corrections as needed

***TASK AREA* (2): Primary Review and Evaluation of Product Performance (efficacy) Data.**

The contractor shall perform a primary review of efficacy data for insecticides, particularly those with public health or wood-destroying insect claims, that will be eligible for re-registration and/or registration review. The contractor shall review protocols submitted for approval prior to conducting efficacy testing. Under this task area, the contractor shall: (1) review, evaluate, and assess the efficacy data to determine the adequacy of methods employed to support efficacy claims and to ensure that all information requirements are met with respect to compliance with EPA OPPTS 810 Series Testing Guidelines and policies; (2) identify unauthorized modifications made to test methods and determine if the performance standards of the Pesticide Assessment Guideline Subdivision G are met; (3) review efficacy protocols submitted for testing new insecticide pesticide or new uses of registered products; (4) conduct efficacy reviews of protocols and/or study reports to determine to what extent they comply with 40CFR Part 160 "Good Laboratory Practices"; and (5) apply the results from the review to determine if label claims proposed by the registrant are supported. Assist in the revision of OPPTS 810 series product performance guidelines and the compilation of all information relevant to EPA presentations to the Scientific Advisory Panel. These documents shall outline the testing requirements for insecticides used to control public health and/or wood destroying pests. Compile data collected on insecticide testing processes, procedures and performance standards from national and international regulatory agencies together with International Public Health and Agricultural Agencies. Compile data into a report that the OPP can use as the basis for global harmonization of efficacy testing methods and performance standards for public health pesticides.

> **TASK AREA (2) Deliverable:** The contractor shall prepare a written DER of efficacy studies and/or protocols reports to include any other supporting documentation related to the evaluations conducted under this task area. *OPP* will supply the contractor with an estimated number of work hours for each type of guideline study. If the contractor finds that a review will take more hours than the estimated number of hours, they will notify OPP*'s* WAM and wait for approval before proceeding. If contractor reviews are found to be deficient by the Agency, the WAM will advise the contractor of the deficiencies and the contractor shall make corrections as needed

***TASK AREA* (3): Primary Review and Evaluation of Acute Toxicity Data, Companion Animal Safety, and Product Chemistry Data.**

The contractor reviewers shall use the OPPTS 870 Harmonized Guidelines as the acceptable parameter for acute toxicology data; the OPPTS 870 Harmonized Guidelines as the acceptable parameter for companion animal safety toxicology data for pet products; and the OPPTS 830 Harmonized Guidelines as the acceptable parameter for scientific data on product chemistry.

> **TASK AREA (3) Deliverable:** The contractor shall prepare a written DER of acute toxicity, product chemistry and/or companion animal safety studies and/or protocols reports to include any other supporting documentation related to the evaluations conducted under this task area *OPP* will supply the contractor with an estimated number of work hours for each type of guideline study. If the contractor finds that a review will take more hours than the estimated number of hours, they will notify OPP*'s* WAM and wait for approval before proceeding. If contractor reviews are found to be deficient by the Agency, the WAM will advise the contractor of the deficiencies and the contractor shall make corrections as needed

***TASK AREA* (4): Primary Review and Evaluation of Pesticide, Mammalian, Non-Target Organisms Toxicity, Environmental Fate, Toxicity, and Product Chemistry and/or Characterization Data and creation of Data Evaluation Records (DERs).**

The primary objective of this task area is to evaluate the scientific and technical merit of studies submitted to EPA to support an application for registration of a pesticide product. The contractor shall produce DERs for all studies. The contractor shall provide peer review and other environmental studies support to EPA. Specific protocols for systematic review, documentation, and reporting may be identified by EPA through the technical direction of the WAM, or the contractor may be required to propose protocols for EPA approval.

Studies submitted to OPP for the registration of a pesticide will be forwarded to the contractor. Upon receipt of each assigned study, the contractor shall perform an in-depth examination of the study by a reviewer trained in the appropriate scientific discipline. The contractor's reviewer shall examine the reported results and provide a description of his or her conclusions that summarize the overall significance of the study and provide a concise summary of the study and the results, discussing as appropriate: LD_{5O}, LC_{5O}, dose levels, No Observable Effects Levels (NOELS), Lowest Observable Effects Levels (LOELs) and significant toxicological and pathological effects. The contractor shall classify each study into the appropriate category: Acceptable or Unacceptable. Further, the agency defines an acceptable study to be a study conducted according to OPPTS guidelines. The review and evaluation of each study will include analysis of all necessary graphic displays of data, summary tables, and references needed to substantiate technical detail supporting the reviewer's conclusions. The contractor's reviewer shall also identify whether the study was performed in accordance with accepted methodologies as prescribed in EPA's published guidelines and whether the data reported in the studies are reliable for characterizing health hazards and risks to humans and the environment. The results of these detailed analyses shall be reported in the format and level of detail required by the appropriate guidelines and example DERs. The following type of studies will be provide by OPP for analyses and evaluations:

- Acute toxicity and or pathogenicity
- Developmental toxicity
- Neurotoxicity

- Genotoxicity
- Subacute toxicity
- Reproductive toxicity
- Chronic toxicity
- Oncogenicity
- Product chemistry and identity
- Manufacturing process
- Residue chemistry
- Efficacy
- Ecotoxicity
- Environmental fate
- Insect resistance management
- Benefit assessments

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TASK AREA (4) Deliverable: The DERs supplied by the contractor will be the "primary" evaluation of each study, and shall be submitted by the contractor to the WAM for OPP, for secondary expert review by OPP scientists. The DERs will be used by OPP for hazard identification regarding human and environmental effects as part of the required risk assessment for the registration of pesticides. The contractor shall supply a hard copy and an electronic (CD) version of each DER. In addition, the contractor shall supply a signature page attached as a cover for each *DER*, which shall be signed and dated both by the contractor's primary and secondary science reviewers and the quality assurance reviewers. In addition, the signature page shall include a disclaimer authorizing subsequent revisions to the DERs by OPP reviewers.

OPP will supply the contractor with an estimated number of work hours for each type of guideline study. If the contractor finds that a review will take more hours than the estimated number of hours, they will notify OPP's WAM and wait for approval before proceeding. If contractor reviews are found to be deficient by the Agency, the WAM will advise the contractor of the deficiencies and the contractor shall make corrections as needed

***TASK AREA* (5): Preliminary Risk Assessment for Biopesticides (Draft Tolerance Rules and Draft Decision Documents)**

The primary focus of the contractor's effort is to perform biopesticide-related science reviews and risk assessments which determine qualitative and quantitative potential risks. Upon receipt of an approved work assignment, the contractor shall conduct and document risk assessment(s) in a consistent and scientifically credible fashion relative to Final Rules for Food Tolerances (or Exemptions) and BRADs, and in accordance with the format specified and provided by BPPD. The contractor shall utilize results and findings of preliminary reviews, or results of secondary reviews, if available, to draft the preliminary risk assessments.

TASK AREA Deliverable (5): The contractor shall supply a signature page attached as a cover for each preliminary risk assessment, which shall be signed and dated by the contractor's primary and secondary science reviewer(s) and the quality assurance reviewer(s). In addition, the signature page shall include a disclaimer authorizing subsequent revisions to the document by BPPD reviewers.

OPP will supply the contractor with an estimated number of work hours for each type of

guideline study. If the contractor finds that a review will take more hours than the estimated number of hours, they will notify OPP's WAM and wait for approval before proceeding. If contractor reviews are found to be deficient by the Agency, the WAM will advise the contractor of the deficiencies and the contractor shall make corrections as needed

TASK AREA* (6): *Review of Confidential Statement of Formulation

The primary focus of the contractor's effort shall be to provide scientific review and recommendations to the Agency with regard to the accuracy of the Confidential Statement of Formulation (CSF) including ensuring that statements made on the CSF are in accord with the results of studies provided for product chemistry and manufacturing process. For all activities, assigned within this task area, specific protocols may be identified by EPA or the contractor may be required to propose protocols for EPA approval.

***TASK AREA* Deliverable (6):** The contractor shall prepare written reports to include any other supporting documentation related to the evaluations conducted under this task area. *OPP* will supply the contractor with an estimated number of work hours for each type of guideline study. If the contractor finds that a review will take more hours than the estimated number of hours, they will notify OPP's WAM and wait for approval before proceeding. If contractor reviews are found to be deficient by the Agency, the WAM will advise the contractor of the deficiencies and the contractor shall make corrections as needed

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TASK AREA* (7): *Review of Pesticide Product Labels

The primary focus of the contractor's effort shall be to provide label review and make recommendations to the Agency on changes that are needed. These may be draft labels for pending registration actions or they may be existing labels where the active ingredient(s) has recently completed Registration Review. The contractor shall rely upon the guidance provided in the most recent edition of the Label Review Manual, PR Notices that pertain to labeling (for example, PR Notice 2001-1 for First Aid Statements, 2000-5 for Mandatory vs. Advisory Label Language, etc.), existing regulations, any policy notices, and recent risk management decisions that require label changes to existing products as a result of Registration Review decisions. The Label Review Manual is available online at http://www.epa.gov/pesticides/regulating/labels/product-labels.htm, and at http://www.epa.gov/pesticides/registrationkit/. The PR Notices are available online at http://www.epa.gov/PR_Notices/. Policy notices and documentation of any risk management decisions that need to be on existing products as a result of Registration Review decisions will be provided by the Agency to the contractor.

The contractor will be responsible for reviewing minor regulatory actions such as Notifications. Regulatory actions that can be done through the Notification process are typically label changes that are not complex. The type of Notifications that the contractor would process are notifications where previously agreed upon language is uniformly required on all like actions. The contractor would be responsible for identifying all Notifications for a specific type of action that do not meet the uniform language requirements and giving them to the appropriate product

team reviewer to complete the action as a non-Notifications.

In accordance with the United States Department of Agricultural (USDA) National Organic Standards Program (NOP), OPP will allow for identification on the pesticide label of particular product(s) meeting the NOP Standards. OPP will provide the contractor with a list of active and inert (other) ingredients that meet these standards, and information on unacceptable manufacturing processes, such as: unacceptable solvents, acceptable and unacceptable use sites, relevant regulations and Pesticide Registration (PR) Notices. CSFs, manufacturing processes, label data, and any other appropriate information will also be provided by OPP to assist the contractor in making valid recommendations as to whether the products meet NOP Standards. OPP Scientists will perform a secondary review and make final determination as to whether the product(s) meet NOP Standards. .

> ***TASK AREA* Deliverable (7):** Outputs within this task area include a report documenting errors, inappropriate label claims, formatting problems, etc., with areas of the label highlighted to reflect where changes are necessary, or a draft letter to the registrant outlining these deficiencies. The letter would be prepared with the appropriate signature block of the EPA official delegated the authority to sign deficiency letters. This information will be supplied to the contractor with the work assignment
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> *OPP* will supply the contractor with an estimated number of work hours for each type of product label review. If the contractor finds that a review will take more hours than the estimated number of hours, they will notify OPP's WAM and wait for approval before proceeding. If contractor reviews are found to be deficient by the Agency, the WAM will advise the contractor of the deficiencies and the contractor shall make corrections as needed

SECTION 508 COMPLIANCE

The deliverables shall be in compliance with Section 508 Accessibility Standards of the Rehabilitation Act, of the 1973 and Amendments of 1998. When preparing deliverables, the contractor shall refer to the most recent version of the 508 Standards at: http://www.access-board.gov/sec508/guide/.

CONFIDENTIAL BUSINESS INFORMATION

All contractors and subcontractors will be subject to clearance for the handling of Confidential Business Information (CBI) per the FIFRA Information Security Manual. During the life of this contract additional clearance, such as required under Toxic Substances Control Act (TSCA), may also be added. Such additional clearance is described in the TSCA CBI Protection Manual.

Disclosure of FIFRA CBI to contractors is provided for under Section 10(e) of FIFRA and in 40 CFR 2.307. Contractors must be cleared for access to FIFRA CBI and must control FIFRA CBI according to the requirements specified for contractors in the FIFRA Information Security Manual, dated July 1988. Identification of contractor personnel will be made by EPA while on site at EPA. Control measures for protecting FIFRA CBI shall be in accord with the following sections of the FIFRA Information Security Manual:

- "Disclosure of FIFRA CBI to Contractors", Section 3;
- "Procedures for Gaining Access to FIFRA Sensitive Information", Section 4; and
- "Operational Procedures for Protecting FIFRA Sensitive Information", Section 5.

The contract shall incorporate specific clauses that describe action to be taken by the contractor with regard to FIFRA sensitive information. These clauses are contained in 40 CFR 2.037(h)(23)(ii), and is Exhibit 6 in the FIFRA Information Security Manual. The contractor shall adhere to the CBI requirements listed in the following EPAAR clauses:

- EPAAR 1552.232.71 (Treatment of CBI)
- EPAAR 1552.235.72 (Data Security – FIFRA CBI)

CONFLICT OF INTEREST (COI)

The contract will contain COI provisions and clauses to allow the Agency to avoid actual or potential conflicts of interest. These provisions will require:

1. Personnel to submit COI avoidance plans as part of these proposals
2. The contractor to alert EPA to actual or potential conflicts of interest with respect to individual task assignments. COI will be avoided through adherence with the appropriate EPAAR clauses:

- EPAAR 1552.209-71 (Organizational Conflict of Interest)
- EPAAR 1552.209-73 (Notification of Conflicts of Interest Regarding Personnel)
- EPAAR 1552.210-80 (Annual Certification)
- EPAAR 1552.227-76 (Project Employee Confidentiality Agreement)